衞生署藥物辦公室
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**DEPARTMENT OF HEALTH**
**DRUG OFFICE**
**DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION**
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(來函請註明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

BY FAX

25 June 2012

Dr. Raymond LIANG
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)

Dear Dr. LIANG,

EMA: Recommendations on the restriction use of trimetazidine-containing medicines

Please kindly note that the European Medicines Agency (EMA) has recommended restricting the use of trimetazidine-containing medicines in the treatment of patients with angina pectoris to second-line, add-on therapy.

For all other indications, the Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of these medicines were not sufficiently demonstrated and did not outweigh the risks. The CHMP therefore recommended the deletion of existing indications for the treatment of vertigo, tinnitus and vision disturbance from the marketing authorisation.

EMA advised that 1) there is no need for an urgent change in treatment, but patients' treatment should be reviewed at their next routine appointment; 2) trimetazidine should no longer be prescribed for the treatment of patients with tinnitus, vertigo or disturbances in vision; 3) trimetazidine can be prescribed continuously for the treatment of angina pectoris, but only as an add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled by or intolerant to first-line anti-anginal therapies.

The CHMP also recommended new contraindications and warnings to reduce and manage the possible risk of movement disorders associated with the use of trimetazidine, which includes 1) trimetazidine should not be prescribed to patients with Parkinson disease, parkinsonian symptoms, tremors, restless leg syndrome orother related movement disorders, nor to patients with severe renal impairment; 2) caution should be exercised when prescribing trimetazidine to patients with moderate renal impairment and to elderly patients, and dose reduction should be considered in these patients; 3) trimetazidine should be discontinued permanently in patients who develop movement disorders such as Parkinsonian symptoms.

Please refer to EMA's website for details:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/06/news_detail_001541.jsp&mid=WC0b01ac058004d5c1

In Hong Kong, there are 7 registered pharmaceutical products containing trimetazidine and are prescription-only medicines. They can be used for the treatment of angina pectoris, vertigo, tinnitus and visual disturbance. In view of the EMA's recommendation, the matter will be discussed in the meeting of Registration Committee of the Pharmacy and Poisons Board.

Please encourage your members to report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "Reporting an Adverse Drug Reaction": http://www.drugoffice.gov.hk/eps/root/en/healthcare_providers/adr_reporting/index.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly drug safety digest of drug safety news and information issued by Drug Office.

Yours sincerely,

(Ms. Christine CHEUNG)
for AD(D)